

process in the same spirit in which Spectrum engaged in hastening the production of onerous discovery. Instead, Jay undertook the vexatious motion practice now before the Court.

Jay suffered no prejudice from Spectrum's designations, and to the extent that any of the designations relate to meaningful material, Spectrum has always been open to a principled resolution of any concerns. The Court should deny Jay's motion.

II. FACTS

The parties held their first discovery conference pursuant to Rule 26(f) on February 14, 2014. (*See* dkt. 21 at 1.) Under Rule 26(d)(1), Jay could have served discovery requests starting that very day. Yet Jay delayed serving a single document request until January 14, 2015—11 months to the day after the conference and 13 months after the initiation of this action. *See* Gilmore Decl. Ex. A (Jay's First Set of Requests for Production). In that discovery, Jay propounded more than three dozen requests for production, broadly covering the waterfront of issues. *Id.* Soon after, in an attempt to cover his intransigence, Jay began a drumbeat of complaints regarding Spectrum's alleged failure to produce documents immediately. *See* Gilmore Decl. Exs. B, C.

Spectrum produced many documents at issue without direct review, relying upon the clawback and non-waiver provisions of the Protective Order (Section 15) and Rule 502(d). Spectrum responded to the document requests by producing 4,815 documents on April 6, 2015; 2,041 documents on May 4, 2015; 10,628 documents on May 15, 2015; 409 documents on May 26, 2015; 1,001 documents on June 2, 2015; 4,693 documents on June 3, 2015; 11 documents on June 30, 2015; and 369 documents on July 10, 2015. *See* Gilmore Decl. Ex. D. To protect potentially confidential information, many of those documents were marked as "Attorneys' Eyes

Only,” with the expectation that if any of these documents was not in fact highly confidential, it could be de-designated through the mechanisms set forth in the Protective Order.

Jay raised no issue whatsoever about Spectrum’s designations until after his counsel showed Attorneys’ Eyes Only discovery to Jay, in violation of the Protective Order. Even here, Jay raises no issue about any of Spectrum’s designations on materials Jay’s counsel disclosed to Jay in violation of the Protective Order.

III. ARGUMENT

A. **Jay Suffered No Prejudice from the Designation of “Meaningless” or Publicly Available Materials.**

Jay describes the vast majority of the documents at issue in this motion – those identified in Section A of Jay’s Memorandum of Law – as either “meaningless” to this case, publicly available, or containing only non-confidential information (*see* Memo. at 4-6). As to these documents, Jay has suffered no harm at all, let alone “undu[e] restrict[ion] [of his] ability to prepare for trial.” (Memo. at 6.)

The Protective Order itself provides the remedy that Jay seeks for the majority of the documents at issue in Section A of his Memorandum of Law. Section 18(a) states that—regardless of its designation—material that is already in the public domain is not protected and may be freely shared. (*See* dkt. 57 at 12.) This means that articles, patents, and other public documents are able to be disclosed in spite of whatever designation Spectrum affixed. The Court need not be detained by any dispute on materials in the public domain: the Court has already decided the merits in its issuance of the Protective Order.

As to materials identified in Section A of Jay’s Memorandum not in the public domain, the Protective Order provides a mechanism for resolving that dispute as well. Section 17 defines a de-designation process. (*See* dkt. 57 at 11-12.) Here, Spectrum takes no issue with the de-

designation of materials obviously not confidential: blank pages and images with no identifying or otherwise confidential information. The Court need not order the same – Spectrum will stipulate to their de-designation.

Had Jay earnestly engaged in the meet and confer process, he would have known of Spectrum’s willingness to de-designate the materials he identified in Section A of his Memorandum without the need to burden the Court with motions such as this. Jay likely knows that, but burdens the Court with this motion anyway.

B. Jay’s Effort to Justify a Violation of the Court’s Order Should Be Rejected.

As part of its voluminous production, Spectrum produced highly confidential clinical studies of their products, including clinical protocols, used in obtaining FDA clearance to sell their products. Jay questioned Spectrum’s corporate representatives concerning these materials at deposition, and appended some of these materials as exhibits. This information is properly designated Highly Confidential – Attorneys’ Eyes Only under the Protective Order. (*See* dkt. 57 at ¶ 4.) The information and material that is the subject of Section B of Jay’s Memorandum of Law should remain designated as such.

Clinical studies, clinical protocols, and submissions to the FDA for obtaining clearance are classic examples of highly confidential information, and materials which – if divulged to a competitor – would irreparably alter the competitive landscape. *See, e.g.*, 21 CFR § 20.61(c) (“Data and information submitted or divulged to the Food and Drug Administration which fall within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure.”); *see also* Dkt. nos. 99, 100 (Spectrum’s Motion for Sanctions for Breach of the Protective Order). So too is financial information. *GoSMiLE, Inc. v. Dr. Jonathan Levine, D.M.D. P.C.*, 769 F. Supp. 2d 630, 649-50 (S.D.N.Y. 2011) (holding that

“highly proprietary material concerning the defendants’ marketing strategies, product development, costs and budgeting” is properly filed under seal); *Gelb v. Am. Tel. & Tel. Co.*, 813 F. Supp. 1022, 1035 (S.D.N.Y. 1993) (finding that a protective order is appropriate to prevent disclosure of documents that “center on financial operations”). There is no dispute that Jay has demonstrated interest in competing with Spectrum in the light-based hair removal market in the past, and his counsel concedes that he could do so again. (Memo. at 8.)

Jay asserts, however, that this information is “stale” and “do[es] not include any information that would be useful to a competitor.” (Memo. at 6.) But Shaser invested a great deal of money and time developing its protocol and obtaining approval from the IRB and FDA, and the information at stake could be used by a competitor to guide its own approval process without making a similar investment. For that reason, the FDA maintains such documents as highly confidential and does not allow competitors access to them. See 21 C.F.R. § 20.61. Likewise, documents that “center on internal financial operations” are “traditional examples of confidential information rising to the level of a trade secret.” *Gelb*, 813 F. Supp. at 1035.

Even Jay himself designated a mere letter to the FDA from 10 years ago as confidential under the Protective Order. See Gilmore Decl. Ex. E. What’s good for Jay should be good for Spectrum. Jay’s inconsistency in his interpretation of proper designation practice underscores what this motion is really about: a *post hoc* effort to justify his counsel’s sharing of Spectrum’s proprietary and confidential information – certain 510(k) submission materials – with Jay. Spectrum’s designations were not objected to until **after** Jay’s counsel violated the Protective Order. (See dkt. 101-7.)

Notwithstanding, in order to resolve this motion, Spectrum offers to de-designate certain non-substantive portions of the transcripts of its representatives. See, e.g., Gilmore Decl. Exs. F,

G. Substantive discussion of confidential and proprietary information and the exhibits to those depositions, however, should remain designated as is. To give Jay access to documents and information relating to the operation of, or financial performance of, Spectrum's products would allow him a competitive advantage in the marketplace. Disallowing litigation-based freeriding in the marketplace is precisely the reason that the Attorneys' Eyes Only designation exists.

C. The Court Should Reject Jay's Proposed Remedy.

Jay's requested remedy—that Spectrum be required to review all of its documents for confidentiality—is inappropriate and unnecessary. Spectrum's rapid production of documents was not, as in the case cited by Jay, an attempt to "avoid incurring [] unnecessary expense." (Memo. at 9 (citing *Orwasher v. A. Orwasher, Inc.*, No. 09-civ-1081 (VM) (JCF), 2010 WL 2017254, at *3 (S.D.N.Y. May 20, 2010)). It was a direct and necessary result of Jay's failure to prosecute its case diligently and then threats to burden Spectrum and the Court with motion practice.

As set forth above, the Protective Order entered by the Court provides for mechanisms by which documents are de-designated. Spectrum will engage in the process set forth in the Protective Order willingly and cooperatively. To date, Jay has only identified three categories of materials to which he objects: (1) materials to which the designation is self-correcting under the Protective Order, (2) materials Spectrum will de-designate, and (3) materials clearly designated appropriately. To the extent that Jay identifies additional materials falling into that last category that he believes should be de-designated, he can re-approach the Court then. But Spectrum should not be penalized in the meantime by Jay's failure to prosecute his claim fastidiously and unwillingness to participate in the de-designation process.

IV. CONCLUSION

For the foregoing reasons, Spectrum respectfully requests that the Court deny Jay's motion.

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